

Notice of Allowability

Application No.

10/030,693

Examiner

Tamthom N. Truong

Applicant(s)

MULLER ET AL.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment of 4-28-04.
2. ☒ The allowed claim(s) is/are 1,2,6,7,10-12,14 and 16-23.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 05-15-02
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Claim 18: on line 4, delete the phrase "**tetrahydrofolic acid or**".

Authorization for this examiner's amendment was given in a telephone interview with Mr. James E. Ruland on 05-24-04.

Allowable Subject Matter

Applicant's amendment of 04-28-04 has been fully considered. The amended claims and specification have overcome the previous rejections of 112/2nd paragraph and 102(b) based on the teaching of **Müller et. al.** (US'836). With claims 3-5, 8, 9, 13, 15 cancelled, pending claims 1, 2, 6, 7, 10-12, 14, 16-23 are allowed.

Reason for Allowance

The following is an examiner's statement of reasons for allowance:

The invention is drawn to a process of preparing and
concentrating (6S, α S) or (6S, α R) tetrahydrofolic acid or

esters thereof by dissolving equimolar of diastereomers of addition salts of **tetrahydrofolic acid esters** with aromatic sulphonic acids in organic solvents. The closest reference is the teaching of **Müller et. al.** (US'836), which has been overcome by the deletion of tetrahydrofolic acid as a starting material. With no bridging reference, there is no motivation for a prima facie case of obviousness based solely on the teaching of **Müller et. al.**

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

References cited on PTO-892

An update search yields two references: **Fitzbugh et. al.** (US 5,698,693), and **Jequier et. al.** (US 5,489,684). Fitzbugh et. al. teach a process of separating diastereomers of tetrahydrofolic acid esters using chromatography which is not the claimed process. Jequier et. al. teach a process of separating diastereomers of tetrahydrofolic acid from the racemic mixture of tetrahydrofolic acid, and not its esters as claimed herein. Thus, neither one of them can be combined with Müller et. al. (US'836) for a prima facie case of obviousness.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

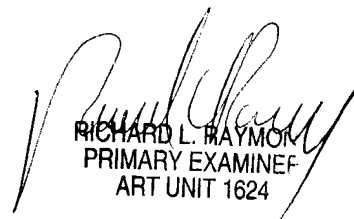
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



T. Truong

May 24, 2004



RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624